NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OYSTER POINT PHARMA, INC., Plaintiff, v. APOTEX INC., Defendant.	**Civil Action No. 23-3860 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the motion[1] to exclude the expert testimony of Dr. Jacobs on the subject of unexpected results by Defendant Apotex, Inc. ("Apotex"). Plaintiff Oyster Point Pharma, Inc. ("Oyster Point") has opposed the motion. For the reasons that follow, the motion will be denied.

Apotex moves to exclude Dr. Jacobs' testimony on unexpected results based on this argument:

> [S]he failed to establish that those results would have been unexpected through comparison of the claimed invention to a single closest prior art reference, a fundamental requirement of obviousness caselaw. Rather, Dr. Jacobs alleged unexpected results by impermissibly comparing the claimed invention to over ten different references, including six publications and at least seven compounds. By failing to compare the claimed invention to a single closest prior art reference, Dr. Jacobs' unexpected results testimony is inadmissible as unreliable and unhelpful to the factfinder under Fed. R. Evid. 702.

[1] Apotex filed two motions to exclude expert testimony, but subsequently withdrew its motion to exclude expert testimony on the subject of written description and enablement.

(Def.'s Br. at 1.) The Court finds unpersuasive Defendant's arguments that the proffered testimony is legally impermissible under Federal Circuit law. The requirements of Federal Circuit law for a legal determination of nonobviousness by the Court are distinct and different from the requirements for admitting expert testimony under Federal Rule of Evidence 702.

As to the requirements of Federal Circuit law for a determination that unexpected results are evidence of nonobviousness, Apotex correctly quotes Abbott: "when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1345 (Fed. Cir. 2006) (quoting In re Baxter Travenol Labs., 952 F.2d 388, 392 (Fed. Cir. 1991)). Apotex contends that Dr. Jacobs' opening expert report compared the invention to at least ten pieces of prior art but did not choose one piece of prior art as the closest. For the purpose of this analysis only, the Court will assume that Apotex has accurately characterized Dr. Jacobs' report.

Apotex contends that, because Abbott requires the Court to determine the closest prior art, and because Dr. Jacobs' opening report did not address the question of which piece of prior art was closest, Dr. Jacobs' expert opinion about whether a POSA would have expected the performance of the invention from knowledge of the different pieces of prior art must be excluded under FRE 702 as neither reliable nor helpful. This does not follow, because the legal requirements for a determination of nonobviousness are distinct and different from the requirements of FRE 702 for admitting expert testimony. FRE 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Apotex argues that, if the Court applies the cited legal principle from Abbott when considering Dr. Jacobs' expert testimony about unexpected results, her testimony cannot be helpful or reliable under FRE 702. There are two main problems here. First, Apotex has said nothing about whether the testimony is the product of reliable principles and methods, nor about whether the expert's opinion reflects a reliable application of the principles and methods to the facts of the case. Apotex has offered nothing to support its challenge to Dr. Jacobs' testimony based on its reliability, within the meaning of FRE 702.

Second, as to the argument that the proposed testimony cannot be helpful to the trier of fact, the Court disagrees. It appears that the gist of the proffered testimony is that a POSA with knowledge of the various pieces of prior art would not have expected the results produced by the invention. A witness who states this expert opinion need not put the pieces of prior art in rank order of closeness to the invention, in order to be helpful to the trier of fact. It could be helpful to opine that not any of the pieces of relevant prior art would have led a POSA to expect the results that were discovered, without identifying which piece of prior art was the closest piece of prior art. This appears likely to help the trier of fact both to understand the evidence and to determine whether there is evidence of unexpected results, a secondary consideration in the obviousness analysis.

In short, the Court finds no conflict between the holding of Abbott and the potential for Dr. Jacobs' testimony to be helpful to the finder of fact in resolving a dispute over unexpected results. Apotex has not demonstrated that the proffered testimony should be excluded as

unreliable or unhelpful under Rule 702. The motion will be denied.

For these reasons,

IT IS on this 6th day of August, 2025

ORDERED that Defendant's motion to exclude the expert testimony of Dr. Jacobs on the subject of unexpected results (Docket Entry No. 185) is **DENIED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.